

REMARKS

The Official Action dated June 2, 2009 has been carefully considered. Accordingly, the present Amendment is believed sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present amendment, claims 1, 10, 30 and 31 are cancelled, whereby claims 11, 26 and 28 remain pending. Since these changes do not involve any introduction of new matter, entry of the amendments is in order and is respectfully requested.

In the Official Action, claims 1, 10, 30 and 31 were rejected under 35 U.S.C. §102(b) as anticipated by Matsumoto, JP 2001/323056. As claims 1, 10, 30 and 31 have been cancelled, this rejection is moot.

Further, claims 1, 10, 30 and 31 were rejected under 35 U.S.C. §103(a) as unpatentable over Shinoda, US 5,247,013. As noted, claims 1, 10, 30 and 31 have been cancelled, whereby this rejection is moot.

Claims 11, 18, 23, 24, 26 and 28 were rejected under 35 U.S.C. §103(a) as unpatentable over Matsumoto. As claims 18, 23 and 24 were previously cancelled from the application, the rejection of these claims is moot. However, Applicants traverse the rejection of pending claims 11, 26 and 28, and reconsideration is respectfully requested.

As defined by claim 11, the process for producing a high-molecular weight aliphatic polyester comprises subjecting a ring-opening (co)polymer of glycolide or a mixture containing at least 70% by weight of glycolide and at most 30% by weight of another cyclic monomer, the ring-opening (co)polymer having a weight average molecular weight of 30,000 to 110,000, to a chain-lengthening reaction with an oxazoline compound having at least two oxazoline ring

structures in its molecule to highly increase the molecular weight to the extent that a ratio (Mw_2/Mw_1) of a weight average molecular weight (Mw_2) of the ring-opening (co)polymer after the chain lengthening to a weight average molecular weight (Mw_1) of the ring-opening (co)polymer before the chain lengthening is 1.65 to 10.00. The reaction employs 1 to 10 parts by weight of the oxazoline compound per 100 parts by weight of the ring-opening (co)polymer under conditions wherein the reaction temperature is not lower than the melting temperature of the ring-opening (co)polymer, but not higher than 240°C, and the reaction time is 10 to 30 minutes, resulting in a high-molecular weight ring-opening (co)polymer having a weight average molecular weight (Mw) of 181,000 to 500,000 and a ratio of weight average molecular weight (Mw) to number average molecular weight (Mn) of 2.30 to 4.50. A difference ($T_2 - T_1$) between a 1%-weight loss-starting temperature T_2 on heating of the ring-opening (co)polymer after the chain lengthening and a 1%-weight loss-starting temperature T_1 on heating of the ring-opening (co)polymer before the chain lengthening is 20°C to 30°C, and the 1%-weight loss-starting temperature T_2 on heating of the ring-opening (co)polymer after the chain lengthening is at least 252°C. Generally, it is difficult to obtain a high-molecular weight polyglycolide using ring-opening polymerization of glycolide. However, according to the present process, the high molecular weight product is obtained as a chain-lengthened ring-opening polymer in which the oxazoline compound is bonded as a chain-lengthening agent.

In contrast to the chain-lengthening reaction which is conducted in the process of claim 11, Matsumoto teaches a method for capping the terminal carboxyl groups of an aliphatic polyester resin with an oxazoline or oxazine compound. According to Matsumoto, an aliphatic

polyester in a molten state is reacted with a proper amount of an end-capping agent such as the oxazoline compound and/or oxazine compound, and that it is “desirable from the viewpoints of provision of an aliphatic polyester having a high polymerization degree and reduction of remaining low-molecular-weight compounds that the oxazoline compound and/or oxazine compound is added and reacted *after completion of the polymerization reaction of the polymer*” (paragraph [0018], emphasis added). Matsumoto therefore indicates that the polymerization does not progress by adding the oxazoline compound and Matsumoto does not teach or suggest further enhancing the polymerization degree of the polyester, particularly by a chain lengthening reaction. In fact, by teaching that the end capping is conducted after polymerization is complete, Matsumoto teaches away from the chain lengthening reaction process of claim 11. Thus, Matsumoto does not disclose a method for conducting a chain-lengthening reaction of a ring-opening glycolide (co)polymer.

The Examiner has suggested Applicants provide a comparison of the claimed process and the exemplified teachings of Masumoto. However, it is difficult to provide such a comparison in view of the failure of Masumoto to disclose important details of the process exemplified by Matsumoto, particularly the process employing polyglycolic acid (PGA). For example, in Masumoto’s Example 3, the PGA chips were dried under reduced pressure for 12 hours at 130°C, after which heated and melted liquid PBO was continuously added to the PGA chips in a PGA:PBO ratio of 99.04:0.96 (by weight), and the resultant mixture was fed to a twin-screw kneading extruder having a cylinder temperature of 270°C to react both components, thereby obtaining carboxyl end-capped PGA chips having a η_r of 1.50 (as measured at a concentration of 0.5 g/100 ml and 30°C using a solution of trichlorophenol/phenol = 7/10)

(paragraph [0040]). In addition, Table 1 shows that the concentration of carboxyl end groups in Example 3 was 5 eq/103 kg. Neither the shearing force of the twin-screw kneading extruder nor the reaction time are disclosed by Matsumoto. Accordingly, one of ordinary skill in the art cannot obtain PGA chips having a η_r of 1.50, whose concentration of carboxyl end groups is 5 eq/103 kg, without excessive trial and error experimentation.

Further, Matsumoto's Example 3 describes that a 71% aqueous solution of glycolic acid was concentrated and dehydrated at 180 °C under reduced pressure in a reaction vessel equipped with a stirrer to obtain a crystalline oligomer, the oligomer was dried under reduced pressure for 5 hours at 180°C, and the oligomer was thermally decomposed in a nitrogen atmosphere of 300°C to obtain crude glycolide which in turn was employed to obtain chips of polyglycolic acid (PGA) having a melting point of 224°C (paragraph [0040]). However, the reduced pressure is not disclosed by Matsumoto, and none of the Matsumoto examples employing poly(L-lactic acid) employ a reduced pressure. Accordingly, it is difficult to produce the starting polyglycolic acid employed in the Matsumoto Example 3 as the reduced pressure is a parameter necessary for the production of PGA but, nevertheless, undisclosed by Matsumoto. Thus, it is not possible to re-produce the process of Example 3 of Matsumoto without the use of undisclosed parameters and conditions which therefore prevent a side-by-side comparison with the actual teachings of the cited prior art.

Moreover, there are important limitations in the process of claim 11 which are neither taught nor suggested by Matsumoto. First, the only teaching of a polyglycolic acid (PGA) reaction temperature which Applicants can find in Matsumoto is in Example 3 wherein a PGA having a melting point of 224°C and of undisclosed molecular weight is heated with an

oxazoline compound (PBO) in a twin-screw kneading extruder having a cylinder temperature of 270°C. While a reference is not limited to its examples, this is the only disclosure in Masumoto which Applicants find relating to a PGA reaction temperature. In contrast to the 270°C employed by Matsumoto, the process of claim 11 requires the use of a reaction temperature not higher than 240°C.

In the Official Action, the Examiner asserted that although Matsumoto uses a reaction temperature of about 45°C higher than the melting point of polyglycolic acid, since the polymers are in the melted state, the degree of heating above the melting point does not affect the polymer's reactivity. On the other hand, the Examiner also asserted that the chosen temperature above the melting point is a result effective variable, wherein increasing the temperature decreases the melt viscosity and vice versa and a faster reaction time would be expected as one increases the temperature. The Examiner's statements are not only unsupported by evidence on the record, they are conflicting in that the Examiner first concludes that the temperature does not effect reactivity and the second statement concludes that there is an effect on reactivity, but that such an effect would be expected. Moreover, and importantly, Masumoto does not disclose that the reaction temperature in Example 3 is a result effective variable, and particularly does not disclose what result, if any, is effected by a change of at least 35°C in reaction temperature. It is not obvious to optimize a parameter not recognized as a result-effective variable, *In re Antonie*, 195 U.S.P.Q. 6 (CCPA 1977). In view of Matsumoto's failure to disclose the reaction temperature as result effective, it could not have been obvious for one of ordinary skill in the art to modify the reaction temperature from that taught by Matsumoto.

The Examiner also concluded that a prima facie case of obviousness exists to optimize the temperature depending on the viscosity and reaction time desired, meeting the temperature requirements of the claims. However, there is no indication in Matsumoto, or otherwise of record, that any different viscosity or reaction time is desired or that the reaction temperature disclosed by Matsumoto could be or should be modified to result in a particular effect.

Second, while the process of claim 11 requires a reaction time of 10 to 30 minutes at the specified temperature of 240°C, Matsumoto fails to disclose a reaction time for the end capping reaction. In the Official Action, the Examiner asserted it would have been obvious to tailor the reaction time of Matsumoto to achieve the desired cross-linked density or molecular weight to create articles with superior molding properties. However, Matsumoto provide no teaching or suggestion that the end capping reaction, and specifically the reaction time, has any effect on cross-linked density or molecular weight. In fact, Matsumoto provide no teaching of a reaction time in Example 3 and provide no teaching of crosslinking in the disclosed polymers. Accordingly, one of ordinary skill in the art would have had no apparent reason to employ a reaction time of 10 to 30 minutes as presently claimed.

Third, the process of claim 11 requires that the starting ring-opening (co)polymer of glycolide has a weight average molecular weight of 30,000 to 110,000, the resulting chain-lengthened reaction product has a weight average molecular weight of 181,000 to 500,000, and the ratio of these molecular weights is in a range of 1.65-10.00. Masumoto does not disclose either the weight average molecular weight before or after the end capping reaction, which would have indicated to one of ordinary skill in the art that the end capping reaction does not significantly effect molecular weight. The Examiner previously asserted that Matsumoto

generally discloses the starting polymer has a weight average molecular weight of at least 50,000 up to 300,000 (paragraph [0010]), and in the Official Action the Examiner further asserted that since Matsumoto teaches that either polymer may be used, it is unclear what other molecular weight range one of ordinary skill would use for polyglycolic acid, other than that taught for polylactic acid. However, there is no evidence of record that the molecular weights of polylactic acid and polyglycolic acid are equivalent. While the Examiner has asserted that Matsumoto teaches the polymers as functional equivalents, Applicants find no teaching by Matsumoto that any functional equivalence between polylactic acid and polyglycolic acid, or any of the other polyesters disclosed as useful by Matsumoto, including, inter alia, polycaprolactone, polypivalolactone and polyesters of a glycol such as ethylene glycol or 1,4-butanediol and a carboxylic acid such as succinic acid or adipic acid, extends to equivalence in molecular weights.

To the contrary, Matsumoto's molecular weight disclosure is specific to polylactic acid. Moreover, the significant difference in solution specific viscosities (and measuring solution thereof) as set forth in Table 1 of Matsumoto between the end-capped polylactic acid products, solution viscosities ranging from 7.75 to 9.28, and the end-capped PGA product, solution viscosity of 1.50, would indicate that polylactic acid and PGA as disclosed by Matsumoto are not equivalent in molecular weight. That is, as solution viscosity is generally recognized as a measurement of molecular weight (see J.I. Kroschwitz et al., "*Concise Encyclopedia of Polymer Science and Engineering*," page 638, and Ravve, "*Principles of Polymer Chemistry, 2nd Edition*," page 25, submitted with the Amendment filed September 4, 2007), Matsumoto's own teachings demonstrate that the molecular weights of polylactic acid and PGA are not equivalent. Accordingly, the weight average molecular weights of the starting and product polymers of the

process of claim 11 are neither taught nor suggested by Matsumoto. In fact, Matsumoto uses solution specific viscosity as an index to the molecular weight, to measure resistance to hydrolysis. Importantly, Matsumoto shows only slight increases and decreases in solution specific viscosity, indicating only slight changes in molecular weight of the polymers, by the end capping reactions. To the contrary, the changes in solution specific viscosities are significant when the Matsumoto polymers are subjected to hydrolysis, showing significant changes in molecular weight. That the end capping reaction of Matsumoto results in only slight changes in solution specific viscosity indicates that a chain-lengthening reaction as presently claimed, wherein Mw_2/Mw_1 is 1.65 to 10.0, does not occur.

Further, Matsumoto merely discloses that the “weight average molecular weight of the polylactic acid used in the present invention is preferably as high as possible, and is generally at least 50,000, preferably at least 80,000, preferably 100,000 to 300,000, more preferably 100,000 to 200,000.” Matsumoto is describing the polylactic acid starting polymer which is then subjected to end capping and provides no teaching as to any molecular weight increase which is achieved by the end capping reaction. Matsumoto is concerned with hydrolysis resistance, not molecular weight increase. Matsumoto provides no teaching that a polyglycolic acid of weight average molecular weight of 30,000-110,000 is necessarily used or that the end-capping will necessarily result in a polymer having 1.65 to 10.00 times higher molecular weight, as is required by the process of claim 11.

In determining patentability under 35 U.S.C. §103, it is necessary to determine whether there was an apparent reason to combine known elements in the fashion of the claims at issue, *KSR International Co. v. Teleflex, Inc.*, 550 US 398, 418 (2007). Applicants find no evidence of

record which would indicate any apparent reason to one of ordinary skill in the art to modify and supplement the teachings of Matsumoto to provide a chain-lengthening reaction product of the molecular weight required by claim 11 by reacting a polyglycolic acid of a specified starting molecular weight with an oxazoline compound for 10 to 30 minutes at a reaction temperature of not higher than 240°C as required in the process of claim 11. In fact, Matsumoto provides no teaching of the reaction parameters specifically recited in claim 11 and provides no recognition or suggestion that such chain-lengthening reaction could be conducted or that a chain-lengthened product having the recited combination of properties could be obtained thereby. Thus, the process of claim 11, and those of claims 26 and 28 dependent thereon, are nonobvious over Matsumoto whereby the rejection of claims 11, 26 and 28 under 35 U.S.C. §103 has been overcome. Reconsideration is respectfully requested.

Claims 1, 10, 11, 18, 23, 24, 26 and 28 were rejected under 35 U.S.C. §103 as unpatentable over the Bonsignore U.S. Patent No. 5,470,944 in view of Matsumoto. As claims 18, 23 and 24 were previously cancelled from the application, and claims 1 and 10 are cancelled herein, the rejection of these claims is moot. However, Applicants traverse the rejection of pending claims 11, 26 and 28, and reconsideration is respectfully requested.

The process of claim 11 is discussed in detail above. As noted, claim 11 recites that the ring-opening (co)polymer of glycolide and at most 30% by weight of another cyclic monomer having a weight average molecular weight of 30,000 to 110,000 and the oxazoline compound are subjected to the chain-lengthening reaction under conditions wherein the reaction temperature is not lower than the melting temperature of the ring-opening (co)polymer, but not higher than

240°C, and the reaction time is 10 to 30 minutes. The weight average molecular weight of the product is 181,000 to 500,000 and 1.65 to 10.00 times greater than that of the starting polymer.

On the other hand, Bonsignore is directed to the production of high molecular weight polylactic acid (at least about 25,000 and preferably above 50,000-100,000, column 6, lines 26-28) from lower molecular weight (2000-15,000, column 1, lines 11-18) versions. Bonsignore mentions polyglycolic acid is conventionally prepared by condensation polymerization or ring-opening polymerization and is environmentally compatible because it degrades to glycolic acid. While copolymers of lactic acid and glycolic acid are mentioned, for example at column 3, lines 34-37, no teaching or suggestion for production of high molecular weight polyglycolic acid, particularly from a starting polymer containing at least 70 weight % glycolide, is found in Bonsignore. Moreover, Bonsignore provides no basis or apparent reasoning for one of ordinary skill in the art to apply any of Bonsignore's teachings to glycolic acid, particularly to obtain a product as presently claimed. To the contrary, the weight average molecular weight of Applicants' starting material, the ring-opening (co)polymer before the chain lengthening, is at least 30,000, within the desired end product of Bonsignore, and Bonsignore provides no teaching of a process for producing a polymer product having a weight average molecular weight of at least 181,000 as required by claim 11.

Further, Bonsignore provides no teaching or suggestion of the reaction parameters recited in claim 11, and particularly a chain-lengthening reaction conducted at a reaction temperature not lower than the melting temperature of the ring-opening (co)polymer, but not higher than 240°C, and a reaction time of 10 to 30 minutes. To the contrary, Example 1 of Bonsignore employs a

two hour reaction period at room temperature (column 11, lines 38-40). In Example 2 of Bonsignore, the solution was allowed to react overnight at room temperature (column 11, lines 59-61). Finally, in Example 3 of Bonsignore, the reaction of 15.2 g of NCO-capped PLA prepolymer solution with 2.5g of polypropylene glycol (MW 1000), catalyzed with 5 drops of stannous octoate, was conducted at 100-120°C for 20 minutes (column 12, lines 18-22). These reaction conditions specifically disclosed in Bonsignore do not teach or suggest the reaction conditions required by claim 11, namely a reaction temperature of from the polymer melting point to 240°C and a reaction time of 10 to 30 minutes. While a reference is not limited to its examples, Applicants do not find any other teaching by Bonsignore regarding reaction temperatures and times. Thus, the process of Bonsignore is significantly different from the process of claim 11.

In the Official Action, the Examiner asserted that Bonsignore recognizes that polylactic acid has a melting point of about 175°C whereas polyglycolide has a melting point of about 230°C, referring to column 4, lines 26-34. Nonetheless, Bonsignore teaches the use of reaction temperatures below the melting point of the polymers. The Examiner again asserted that since the polymers in Matsumoto are in the melted state, the degree of heating above the melting point does not affect the polymer's reactivity and the chosen temperature is a result effective variable, so it would be obvious to optimize the temperature depending on the viscosity and reaction time desired. As noted above, the Examiner's statements are not only unsupported by evidence on the record, they are conflicting in that the Examiner first concludes that the temperature does not effect reactivity and the second statement concludes that there is an effect on reactivity, but that

such an effect would be expected. Further, Masumoto does not disclose that the reaction temperature is a result effective variable, and particularly does not disclose what result, if any, is effected by a change in reaction temperature, and there is no indication in Matsumoto, or otherwise of record, that any different viscosity or reaction time is desired or that the reaction temperature disclosed by Matsumoto should be modified.

Importantly, Matsumoto teaches an end-capping reaction to reduce hydrolysis and thereby increase heat resistance. Matsumoto is not directed to increasing molecular weight. Accordingly, one of ordinary skill in the art would have had no reason to combine the end-capping teachings of Matsumoto with the method of Bonsignore. Particularly, Matsumoto provides no motivation to modify any teachings of Bonsignore since these references are directed to different objectives. Moreover, such a combination does not result in the process of claim 11, as Masumoto similarly fails to teach, suggest or other motivate one of ordinary skill in the art to employ a polyglycolic acid of weight average molecular weight of 30,000 to 110,000 in a chain lengthening reaction conducted at a temperature not lower than the melting temperature of the ring-opening (co)polymer, but not higher than 240°C, and a reaction time of 10 to 30 minutes. Thus, the production processes of claims 11, 26 and 28 are nonobvious over the combination of Bonsignore and Matsumoto, whereby the rejection under 35 U.S.C. §103 has been overcome. Reconsideration is respectfully requested.

It is believed that the above demonstrates the patentability of present claims 11, 26 and 28, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Please charge any fees required in connection with the present communication, or credit any overpayment, to Deposit Account No. 503915.

Respectfully submitted,

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